

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-27 (canceled)

Claim 28. (Currently Amended) A pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of a protein or polypeptide non-covalently bound to one or more and colloidal particles, ~~said the one or more~~ colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein ~~said the~~ protein or polypeptide is selected from the group consisting of:

- (a) Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Copaxone; or ~~proteins or polypeptides capable of externally binding said colloidal particles;~~
- ~~(b) proteins or polypeptides capable of binding polymers of the polyalkylether, polylactic and polyglycolic acid families; and~~
- ~~(c)~~(b) proteins or polypeptides that ~~include~~ comprise a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings;

wherein said the protein or polypeptide is not Factor VIII (FVIII), and wherein said the protein or polypeptide is not encapsulated in said the one or more colloidal particles.

Claim 29. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 28 wherein said the colloidal particles are substantially neutral and said the polymer carries substantially no net charge.

Claim 30. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 28 wherein said the colloidal particles have a mean particle diameter of between about 0.03 to about 0.4 microns.

Claim 31. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 30 wherein said the colloidal particles have a mean particle diameter of approximately 0.1 microns.

Claim 32. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 28 wherein said the amphipathic lipid is a phospholipid from natural or synthetic sources.

Claim 33. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 32 wherein said the amphipathic lipid is phosphatidylethanolamine (PE).

Claim 34. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 28 wherein said the amphipathic lipid is a carbamate-linked uncharged lipopolymer.

Claim 35. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 34 wherein ~~said~~ the amphipathic lipid is aminopropanediol distearoyl (DS).

Claim 36. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 28 wherein ~~said~~ the colloidal particles further comprise a second amphipathic lipid obtained from either natural or synthetic sources.

Claim 37. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 36 wherein ~~said~~ the second amphipathic lipid is phosphatidylcholine.

Claim 38. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 36 wherein cholesterol is supplemented to the composition.

Claim 39. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 28 wherein ~~said~~ the biocompatible hydrophilic polymer is selected from the group consisting of polyalkylether, polylactic and polyglycolic acid families.

Claim 40. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 39 wherein ~~said~~ the biocompatible hydrophilic polymer is polyethylene glycol.

Claim 41. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 40 wherein the polyethylene glycol has a molecular weight of between about 500 to about 5000 daltons.

Claim 42. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 41 wherein the polyethylene glycol has a molecular weight of approximately 2000 daltons.

Claim 43. (Canceled)

Claim 44. (Withdrawn and Currently Amended) The pharmaceutical composition of ~~Claim~~ claim 28 wherein the polypeptide is Copaxone₁ and the composition may be used for the treatment of a disease selected from the group consisting of multiple sclerosis, diabetic neuropathy, senile dementia, Alzheimer's disease, Parkinson's Disease, facial nerve (Bell's) palsy, glaucoma, Huntington's chorea, amyotrophic lateral sclerosis, status epilepticus, non-arteritic optic neuropathy and vitamin deficiency.

Claim 45. (Withdrawn and Currently Amended) The pharmaceutical composition of ~~Claim~~ claim 28 wherein the polypeptide is Factor VIIa₁ and the composition may be used in hemophilia patients with inhibitors and for the treatment of trauma bleeding.

Claim 46. (Currently amended) The pharmaceutical composition of ~~Claim~~ claim 28 wherein the protein or polypeptide comprises the amino acid consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X is any amino acid, and S, T, L, I, V, E and Q have their standard meanings.

Claim 47. (Currently Amended) ~~Method of treatment of a patient suffering from a disease~~
A method for treating a patient suffering from a disease that is known to be treatable with a

protein or polypeptide known to effectively treat the disease, comprising ~~administering~~
administering to a said patient in need thereof a pharmaceutical composition for parenteral
administration comprising a therapeutically effective amount of the protein or polypeptide
~~effective in the treatment of the disease and~~ non-covalently bound to one or more
colloidal particles, the one or more said colloidal particles comprising approximately 1-20
mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the said protein or polypeptide is selected from the group consisting of:

- (a) Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte
macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like
peptide 1 (GLP-1) and Copaxone; or ~~proteins or polypeptides capable of
externally binding said colloidal particles;~~
- ~~(b) — proteins or polypeptides capable of binding polymers of the polyalkylether,
polylactic and polyglycolic acid families; and~~
- ~~(c)~~(b) proteins or polypeptides that ~~include~~ comprise a consensus sequence of
S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L,
I, V, E and Q have their standard meanings;

wherein the said protein or polypeptide is not Factor VIII (FVIII), and wherein the
said protein or polypeptide is not encapsulated in the one or more said colloidal particles.

Claim 48. (Withdrawn and Currently amended) The method of ~~Claim~~ claim 47 wherein
said the disease is hemophilia.

Claim 49. (Withdrawn and Currently amended) The method of Claim claim 47 wherein ~~said~~ the patient has developed inhibitor antibodies to said protein or polypeptide.

Claim 50. (Currently Amended) ~~Method of treatment of a patient suffering from a disease~~
A method for treating a patient suffering from a disease that is known to be treatable with a
protein or polypeptide known to effectively treat the disease, comprising administering
administering to said a patient in need thereof a pharmaceutical composition for parenteral
administration comprising

a therapeutically effective amount of ~~[[a]]~~ the protein or polypeptide effective in the
~~treatment of the disease and colloidal particles, said colloidal particles comprising~~
~~approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible~~
~~hydrophilic polymer, wherein said protein or polypeptide is selected from the group~~
consisting of:

- (a) Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte
macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like
peptide 1 (GLP-1) and Copaxone; or proteins or polypeptides capable of
externally binding said colloidal particles;
- ~~(b) proteins or polypeptides capable of binding polymers of the polyalkylether,~~
~~polylactic and polyglycolic acid families; and~~
- ~~(c)~~(b) proteins or polypeptides that ~~include~~ comprise a consensus sequence of
S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L,
I, V, E and Q have their standard meanings; and

one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein said the one or more colloidal particles and said the protein or polypeptide are administered separately, ~~and wherein said protein or polypeptide is not encapsulated in said colloidal particles.~~

Claim 51. (Currently amended) The method of claim 50 wherein said the protein or polypeptide is not Factor VIII (FVIII).

Claim 52. (Withdrawn and Currently amended) The method of claim 50 wherein said the one or more colloidal particles comprise liposomes and said the protein or polypeptide is Factor VIII (FVIII).

Claim 53. (New) The method of claim 50, wherein the protein or polypeptide is Copaxone.

Claim 54. (New) A method for treating a patient suffering from a disease that is known to be treatable with a protein or polypeptide known to effectively treat the disease, comprising administering to a patient in need thereof a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the protein or polypeptide non-covalently bound to one or more colloidal particles, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer,

wherein the protein or polypeptide is selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-*like* peptide 1 (GLP-1) and Copaxone, and

wherein the protein or polypeptide is not encapsulated in the colloidal particles.

Claim 55. (New) A method for extending the half-life of a protein or polypeptide in vivo, comprising:

providing a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the protein or polypeptide non-covalently bound to one or more colloidal particles, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, the protein or polypeptide is selected from the group consisting of:

- (a) Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-*like* peptide 1 (GLP-1) and Copaxone; or
- (b) proteins or polypeptides that comprise a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings; and

administering the pharmaceutical composition to a patient,

wherein the protein or polypeptide is not Factor VIII (FVIII), and the protein or polypeptide is not encapsulated in the colloidal particles.

Claim 56. (New) A method for extending the half-life of a protein or polypeptide in vivo, comprising:

providing a therapeutically effective amount of the protein or polypeptide selected from the group consisting of:

- (a) Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-*like* peptide 1 (GLP-1) and Copaxone; or
- (b) proteins or polypeptides that comprise a consensus sequence of S/T-X-L/I/V-I/V/Q/S-S/T-X-X-E, where X may be any amino acid, and S, T, L, I, V, E and Q have their standard meanings;

providing one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer; and

administering the protein or polypeptide and the one or more colloidal particles to a patient,

wherein the protein or polypeptide and the colloidal particles are administered separately, and the protein or polypeptide is not encapsulated in the one or more colloidal particles.

Claim 57. (New) A method for extending the half-life of a protein or polypeptide in vivo, comprising:

providing a pharmaceutical composition for parenteral administration comprising a therapeutically effective amount of the protein or polypeptide non-covalently bound to one or more colloidal particles, the one or more colloidal particles comprising approximately 1-20 mole percent of an amphipathic lipid derivatized with a biocompatible hydrophilic polymer, the protein or polypeptide is selected from the group consisting of Factor VIIa, granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), interferon γ , glucagon-like peptide 1 (GLP-1) and Copaxone; and

administering the pharmaceutical composition to a patient,

wherein the protein or polypeptide is not encapsulated in the colloidal particles.